REMARKS

I. Status of the Application

Claims 1-42 were filed in the original application. Claims 18-40 were previously withdrawn from consideration with the Response to Restriction Requirement filed on November 19, 2004. Thus, claims 1-17, 41, and 42 were examined and are the subject of the Office Action.

In the Office Action, the Examiner: (1) rejected claims 1-3, 14, 15, 41, and 42 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 6,767,310 to Reilly et al. and further in view of U.S. Patent No. 6,187,529 to Fahy et al.; (2) rejected claims 1-9, 12-17, and 41 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,609,572 to Lang and further in view of Fahy et al.; and (3) rejected claims 10-11 under 35 U.S.C. § 103(a) as being unpatentable over Reilly et al. in view of Fahy et al. as applied to the claims above, and further in view of Lang. In addition, the Examiner stated that a complete reply must include a cancellation of non-elected claims. In this response, the Applicants respectfully cancel claims 18-40 and amend claims 1, 41, and 42. It is noted that the cancellation of claims 18-40 is not meant to preclude further prosecution of claims 18-40, such as by continuation or divisional prosecution.

II. No New Matter Is Introduced by Way of Amendment

Claims 1, 41, and 42 have been amended to clarify that the pinch valve receives one of the at least one disposable tubes between the devices connected by the disposable tube for control of fluid flow therebetween. The requirement of the location of the receipt of the disposable tube and control of fluid flow is supported throughout the specification and in the drawings. Therefore, no new matter has been introduced by way of amendment.

III. The Rejection of Claims 1-3, 14, 15, 41, and 42 Under 35 U.S.C. § 103(a) as Unpatentable over Reilly et al. in View of Fahy et al. is Overcome

Claims 1-3, 14, 15, 41, and 42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Reilly et al. in view of Fahy et al. The Examiner stated that Reilly et al. "discloses at least one syringe, at least one fluid reservoir, at least one valve, and at least one catheter that is disposable..., but Reilly et al. fails to disclose the use of pinch valves as the valves in the system." The Examiner further stated that Fahy et al. "discloses the use of pinch valves instead of stopcock valves in a system that deals with infusing or perfusing fluids into organs or tissues. Fahy et al. discloses the benefit of using pinch valves also." Thus, the Examiner asserts that it "would have been obvious to combine the system of Reilly et al with Fahy et al. because Fahy et al discloses the benefit of using a pinch type valve, which is the easy remove of the valve from the tubing (Fahy et al. Column 17, lines 21-38)."

Applicants' Invention

Applicants' invention can be used for the delivery of multiple drugs to a subject, such as a rodent. In addition, Applicants' invention can be used for retraction of blood samples from the same subject. To accomplish these functions, Applicants' invention is composed of few parts, many of which are disposable. These few parts are combined in a manner that drug delivery and/or blood sampling is coordinated, the volume of drugs going through the fluid subsystem is minimized, and the fluid subsystem not contaminated, i.e., the fluid subsystem is sterile.

Applicants' invention uses **disposable tubing** and **pinch valves** in various combinations together with a catheter and syringes (which syringes may also be disposable). With regard to the pinch valves, as stated at Page 8, lines 8-19:

> ... each of the valves 18, 20, 22, and 24 comprises a two-position, pinch valve with a first and second position that can each open and close. The first and second positions of each of the valves are orifices that receive disposable tubing. The orifices may be slots or other structures that make it easy to place the tubing in each valve without dismantling the fluid subsystem. Because each valve comprises a two-position, pinch valve, the orifice at the first position essentially comprises a first subvalve and the orifice at the second position essentially comprises a second subvalve. During operation, each valve's first position or second position will be open while the other position will be closed. The first position and second position cannot both be open or both be closed at the same time. While each position of each valve is either referred to as the first or second position, it will be appreciated by one skilled in the art that there is no difference between the two positions."

As stated throughout the specification, there are several advantages to the use of disposable tubing and pinch valves according to the present invention. With pinch valves, the disposable tubing is pinched by the pinch valve – fluid does not flow through the pinch valve, but, rather, flows through the disposable tubing. "Accordingly, fluid remains in the syringes, sterile tubing and fluid reservoirs and does not exit the fluid subsystem or contaminate other components, such as the valves that control the flow of fluid." Page 20, line 23 – Page 21, line 2. "Thus, these embodiments of the present invention can be programmed to deliver a desired volume of fluid from one or multiple syringes into a single catheter without the fluid being

exposed to any component which is not a part of either the disposable tubing, tee connectors, y-connectors or syringes that comprise the fluid subsystem." Page 21, lines 17-20. Volume of fluids, such as the drugs, is conserved when pinch valves are used, as the interior of the valve is not filled with fluid. Also, valve types other than pinch valves have the potential to contaminate the fluid – such contamination occurs by the contact of the fluid with the inner workings or interior of the valve. Further, when concerned about cross-contamination of the tubing, the tubing can be replaced, but the pinch valves of Applicants' invention may be reused with new tubing. In fact, all the tubing connecting the devices (syringes, syringe pumps, fluid reservoirs, waste outlet, catheters, and the like) may be replaced in the system of Applicants' invention.

The Invention of Reilly et al.

Reilly et al. discloses a system for use to deliver toxic or hazardous substances, such as radiopharmaceuticals, to a patient. To achieve this objective, the invention of Reilly et al. includes a shielded container for holding the toxic or hazardous substance (item 44), an injector (item 20), a syringe (item 60), an a valve system (item 15) and fluid delivery set (item 16) enclosed in a protective container. The valve system of Reilly et al. includes a stopcock (item 30) having three ports -- "a first port 32 that is in fluid connection with saline syringe 20" (Col. 8, lines 57-58), a "second port 34 ... in fluid connection with source 40" (Col. 8, lines 58-59), and a "third port 36 ... in fluid connection with, for example, a dual check valve 50" (Col. 9, lines 1-2). The dual check valve 50 is "in fluid connection with syringe 60" (Col. 9, line 4) and "in fluid connection with patient fluid path set 80" (Col. 9, line 7). The valve system also includes one-way check valve 110 which provides fluid connection between the patient fluid

path set and check valve 50 (Col. 9, lines 11-14). Further, one-way check valve 140 of the valve system provides fluid connection between bypass tubing 120 and check valve 110 (Col. 9, lines 23-25).

The system of Reilly et al. provides "purging of air from the entirety of fluid delivery set 15 (and preferably, also from fluid path set 80) before connection of fluid delivery set 15 to pharmaceutical source 40." Col. 9, lines 41-45. In addition, the saline syringe 20 is "used to purge air from system 10" and to "flush to patient fluid path set 80 after injection of pharmaceutical(s)" (Col. 10, lines 9-11).

Because the invention of Reilly et al. is used with toxic or hazardous substances, the fluid delivery set "is preferably disposable after one or more used to, for example, reduce the risk of cross-contamination between patients." Col. 11, lines 9-11. Fluid delivery set 15 includes valve system 16. Col. 8, lines 35-36. Thus, it is anticipated that, in use of the system of Reilly et al., the valves that comprise the valve system (stopcock 30, dual check valve 50, one-way check valve 110, and one-way check valve 140) are disposed of after a single user or a very limited number of uses.

The Invention of Fahy et al.

Fahy et al. discloses a system and method for preparing organs for transplantation. The system of Fahy et al. is, as illustrated in Fig. 1A, replete with many valves designated by S and SR and manual clamps, together with numerous fluid lines, devices, and receptacles and reservoirs. Part of the system of Fahy et al. includes a series of reservoirs R1, R2, R3, and R4. As explained at Col. 12, lines 53-61, "Solenoid valves S9-S12 normally direct fluid to reservoirs

R1-R4 or to the waste line (LW). Reservoirs R1-R4 can also be detached from the system by removing recirculation lines RL5-RL8 from reservoirs R1-R4 and plugging them into waste ports W1-W4, respectively (as indicated by curved arrows), allowing reservoirs R1-R4 to be removed from the system for cleaning, sterilizing, and refilling. When reservoirs R1-R4 are moved, valves S9-S12 direct fluid to waste ports W1-W4."

Fahy et al. uses solenoid valves for the control of fluid between the various fluid lines and devices of the system. Fahy et al. does teach the use of a pinch valve, but only for a very specific purpose, and not for control of the fluid between the various devices (syringes, pumps, fluid reservoirs, waste outlets, etc.) of the system. The pinch valve of Fahy et al. is used internally in reservoir R1. As explained at Col. 17, lines 21-24, "The stopcock normally used to control flow from the outer cylinder to the inner cylinder in the commercial device is replaced by a pinch-type two-way (on/off) solenoid valve 202...." As shown in Fig. 1A. Fig. 2A, and explained at Col. 12, lines 53-61 and at Col. 17, reservoir R1 is disposed between recirculation line RL5 extending from solenoid valve S9 and fluid delivery line D1 having a clamp thereon. Referring specifically to Fig. 2A, recirculation line RL5 is connected to recirculation port 209 of reservoir R1, and D1 is the same as fluid delivery line 204. The pinch valve of Fahy et al. resides within reservoir R1 to control flow between the outer cylinder of reservoir R1 and the inner cylinder of reservoir R1.

Fahy et al. replaces a standard solenoid valve with a pinch valve within reservoir R1:

> because of the small pressure difference available to drive fluid flow and the consequent need for a large working diameter fluid path 202b. It is also preferable for easy removal from its tubing 202b when the reservoir is to be removed from the cabinet for cleaning, leaving the solenoid behind.

Col. 17, lines 26-31. These benefits must be taken in context of the location of the pinch valve – within the interior of reservoir R1 to allow or restrict the flow between the inner and outer cylinders within reservoir R1. The use by Fahy et al. of standard valves for the control of the fluid system between devices (reservoirs, waste, etc.) means that the valves of Fahy et al. necessarily become contaminated with a single use of the system.

Claim 1 Is Not Unpatentable Over Reilly et al. in View of Fahy et al.

Applicants' claim 1, as amended, clarifies the use of "at least one pinch valve, each pinch valve having a first position and a second position, wherein the second position receives one of the at least one disposable tubes therethrough **at a position located between the at least one catheter and the at least one syringe connected by the at least one disposable tube for control of fluid therebetween** ". As previously described, pinch valves operate by pinching tubing, and, thus, the tubing passes through a pinch valve – tubing is not cut and then the cut portions connected to the pinch valve as is required with other types of valves. The pinch valve of claim 1 requires that the "second position [of the pinch valve] receives one of the at least one disposable tubes therethrough **at a position located between the at least one catheter and the at least one syringe connected by the at least one disposable tube for control of fluid therebetween** ". The valve of Applicants' invention is not in fluid connection with the fluid flowing through the tubing, yet it is a part of the fluid system located along the tubing that connects a catheter and syringe and controls the flow of fluid flowing between the catheter and syringe.

As previously discussed herein, Reilly et al. discloses the use of a stopcock having ports and check valves. Each of the type of valves used in Reilly et al. have fluid flowing through the valve (referred to as "in fluid connection" throughout the specification of Reilly et al.), and do not comprise a pinch valve. In the Office Action, the Examiner agreed that Reilly et al. does not disclose, teach or suggest the use of such a pinch valve.

However, the Examiner asserts that Fahy et al. does teach the use of a pinch valve in a fluid system. As discussed above, Fahy et al. uses solenoid valves through which fluid flows to control the flow of fluid between devices (reservoirs, waste receptacles, etc.) that comprise the system. Fahy et al. only proposes replacing a valve found within a dual cylinder fluid reservoir with a pinch valve. This pinch valve controls the flow of fluid internal to the reservoir, i.e., the flow of fluid between the inner and outer cylinders of the reservoir – not the flow of fluid between the reservoir and another device in the system as required in Applicants' claim 1, as amended.

"To establish prima facie obviousness of the claimed invention, all of the claimed limitations must be taught or suggested by the prior art." MPEP § 2143.03 (citing *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974)). Further, "[i]f an independent claim is not obvious under 35 U.S.C. § 103, then any claim depending therefrom is not obvious." MPEP § 2143.03 (citing *In Re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988)). Respectfully, if the pinch valve of Fahy et al. were combined with the system of Reilly et al., the resulting combination does not render claim 1 as obvious as the combination does not teach or suggest all of the limitations of claim 1, as amended. Claim 1, as amended, requires a pinch valve that is **"located between the at least one catheter and the at least one syringe connected by the at**

least one disposable tube for control of fluid therebetween". The combination of Reilly et al. and Fahy et al. would result in the use of dual cylinder reservoirs with at least one of the reservoirs having a pinch valve for the tubing between the inner and outer cylinders of the reservoir, if a reservoir were of the type to contain in such cylinders. Neither Reilly et al. nor Fahy et al., alone or combination, disclose, teach, or suggest the use of pinch valves located between devices (syringes, syringe pumps, reservoirs, waste outlets, catheters, etc.) to control the flow of fluid between such devices.

As discussed above, the use of valves between devices through which fluid flows results in several disadvantages. First, the valves may contaminate the fluid flowing therethrough. Second, when concerned about cross-contamination of the fluid system, the valves must be replaced. Third, significantly more fluid must flow through the portion of the system containing the valves as the interior of the valves must also be filled with such fluid.

Because Reilly et al. does not disclose, teach, or suggest the use of pinch valves having tubing passing therethrough, and because Fahy et al. does not disclose teach or suggest the use of pinch valves located between devices (syringes, catheters, reservoirs, waste receptacles, pumps, etc.) in a fluid system for control of the flow of fluid therebetween as required in Applicants' claim 1, as amended, it is respectfully submitted that claim 1, as amended, is allowable, and the rejection of claim 1 as unpatentable over Reilly et al. in view of Fahy et al. under 35 U.S.C. § 103(a) is overcome.

Claims 2, 3, 14, and 15 Are Not Anticipated by Reilly et al.

Because claims 2, 3, 14, and 15 depend from and include all the limitations of claim 1, as amended, it is respectfully submitted that claims 2, 3, 14, and 15 are allowable, and the rejection of claims 2, 3, 14, and 15 as being unpatentable over Reilly et al. in view of Fahy et al. under 35 U.S.C. § 103(a) is overcome.

Claims 41 and 42 are Not Unpatentable Over Reilly et al. in View of Fahy et al.

Claim 41, as amended, requires "at least one pinch valve that has a first position and a second position, wherein the first position receives the at least one syringe inlet therethrough **at a position located between the at least one fluid reservoir and the at least one syringe connected by the at least one syringe inlet for control of fluid therebetween**, and the second position receives one of the at least one disposable tubes therethrough **at a position located between the at least one catheter and the at least one syringe connected by the at least one disposable tube for control of fluid therebetween** ". Thus, according to claim 41, "at least one syringe inlet" passes through the pinch valve, and "one of the at least one disposable tubes" passes through the pinch valve.

As amended, claim 42 requires:

> a first pinch valve and a second pinch valve, wherein the first pinch valve has a first position that receives one of the at least one syringe inlets therethrough **at a position located between the at least one syringe and the at least one fluid reservoir connected by the at least one syringe inlet for control of fluid therebetween**, and has a second position that receives one of the at least one disposable tubes therethrough **at a position located between the at least one catheter and the at least one syringe connected by the at least one disposable tube for control of fluid therebetween**, and wherein the second pinch valve has a first position that receives the catheter outlet therethrough **at a position located between the catheter outlet and the at least one**

> **syringe connected by the at least one disposable tube for control of fluid therebetween**, and has a second position that receives the waste outlet therethrough **at a position located between the waste outlet and the at least one syringe connected by the at least one disposable tube for control of fluid therebetween.**

Thus, according to claim 42, a syringe inlet and disposable tube pass through the first pinch valve, and the catheter outlet and waste outlet pass through the second pinch valve.

For the reasons set forth above for claim 1 with regard to the requirement of **pinch valves located between devices for control of fluid therebetween** in Applicants' invention, it is respectfully submitted that claims 41 and 42 are patentable, and the rejection of claims 41 and 42 as unpatentable over Reilly et al. in view of Fahy et al. under 35 U.S.C. § 103(a) is overcome.

IV. The Rejection of Claims 1-9, 12-17, and 41 Under 35 U.S.C. § 103(a) as Unpatentable Over Lang in View of Fahy et al. is Overcome

Claims 1-9, 12-17, and 41 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lang in view of Fahy et al. The Examiner stated that Lang "discloses at least one syringe, at least one fluid reservoir, at least one valve, and at least one catheter that is disposable, as well as multiple syringes, valves, fluid reservoirs, and syringe pumps and wherein the configuration is the same as the applicant's invention." The Examiner further stated that "Lang fails to disclose the use of pinch valves", but that such is disclosed by Fahy et al.; thus, in the Examiner's opinion, it would have been obvious to combine Lang with Fahy et al.

The Invention of Lang

Lang discloses an infusion system for delivery of multiple drugs to a subject. To accomplish this objective, Lang uses a combination of cassettes for connection to infusion lines, inlet valves, liquid distributions ducts, pump chambers, outlet valves, venting filters and chambers. The inlet and outlet valves of Lang comprise electropneumatically operating valves, or may "be modified for purely electrical or hybrid electromechanical and pneumatic operation. In this respect for instance the electromagnets or pneumatic cylinders will act via plungers, the inlet and outlet valves and the pump chambers may be evacuated by an plunger advanced by an electric stepper motor in accordance with a program, for instance in a large number of small steps or in a few large ones in a pulsating manner with the outlet valve opened." Col. 9, lines 4-12. As shown in detail in the figures, and, in particular, in Fig. 3, the valves are of the type that the valves are filled with fluid. As stated at Col. 6, lines 21-25, during operation of the system of Lang, "Valves, ducts and chambers of the infusion distribution cassette and of the infusion pump cassette A 2 and of the connected and infusion hose are now filled with the infusion solution free of air bubbles prior to connection with the patient."

Claim 1 is Not Unpatentable Over Lang in View of Fahy et al.

Applicants' claim 1, as amended, clarifies the use of "at least one pinch valve, each pinch valve having a first position and a second position, wherein the second position receives one of the at least one disposable tubes therethrough **at a position located between the at least one catheter and the at least one syringe connected by the at least one disposable tube for control of fluid therebetween** ". As previously described, pinch valves operate by pinching

tubing, and, thus, the tubing passes through a pinch valve – tubing is not cut and then the cut portions connected to the pinch valve as is required with other types of valves. Thus, claim 1 requires that the "second position [of the pinch valve] receives one of the at least one disposable tubes therethrough **at a position located between the at least one catheter and the at least one syringe connected by the at least one disposable tube for control of fluid therebetween** ". The valve of Applicants' invention is not in fluid connection with the fluid flowing through the tubing.

Lang discloses a system in which the valves are in fluid connection with the tubing. Whether the system of Lang is an electropneumatic, or electric, hybrid electromechanical, and pneumatic design, the chambers of the valves are filled with fluid. As previously stated, use of valves through which fluid flows has several shortcomings. A considerably large volume of fluid is required to flow through the fluid subsystem because the dead volume within the interior of the valves must be filled. The interiors of such valves have the potential to contaminate the fluid flowing therethrough. In addition, to truly eliminate any contamination in the fluid subsystem, the interiors of the valves would need to be sterilized or the valves replaced with sterile valves.

Applicants' claim 1, as amended, requires the use of pinch valves and the Examiner agrees that Lang does not disclose, teach, or suggest the use of pinch valves. However, the Examiner states that the pinch valve of Fahy et al. in combination with Lang would result in the present invention. Applicants respectfully disagree with this conclusion. As stated above in connection with the argument for patentability over the combination of Reilly et al. and Fahy et al., the combination of Lang and Fahy et al. does not teach or suggest all of the limitations of

claim 1, as amended. Neither Lang nor Fahy et al. teach or suggest the use of pinch valves located between devices of the fluid system for control of fluid therebetween as required in Applicants' claim 1. The combination of Lang and Fahy et al. may result in use of a pinch valve within a device of Lang.

Because Lang does not disclose, teach, or suggest the use of pinch valves, and the pinch valve of Fahy et al. in combination with Lang does not result in pinch valves located between devices connected by the fluid system as is required in claim 1, as amended, it is respectfully submitted that claim 1, as amended, is allowable, and the rejection of claim 1 as unpatentable over Lang in view of Fahy et al. under 35 U.S.C. § 103(a) is overcome.

Claims 2-9 and 12-17 Are Not Unpatentable Over Lang in View of Fahy et al.

Because claims 2-9 and 12-17 depend from and include all the limitations of claim 1, as amended, it is respectfully submitted that claims 2-3 and 12-17 are allowable, and the rejection of claims 2-9 and 12-17 under 35 U.S.C. § 103(a) as being unpatentable over Lang in view of Fahy et al. is overcome.

Claim 41 Is Not Unpatentable Over Lang in View of Fahy et al.

As amended, claim 41 requires "at least one pinch valve that has a first position and a second position, wherein the first position receives the at least one syringe inlet therethrough **at a position located between the at least one fluid reservoir and the at least one syringe connected by the at least one syringe inlet for control of fluid therebetween,** and the second position receives one of the at least one disposable tubes therethrough **at a position located**

between the at least one catheter and the at least one syringe connected by the at least one disposable tube for control of fluid therebetween ". Thus, according to claim 41, "at least one syringe inlet" passes through the pinch valve, and "one of the at least one disposable tubes" passes through the pinch valve with the pinch valves required to be located between the devices (fluid reservoir, syringe inlet, catheter, and syringe).

Claim 42, as amended, requires

> a first pinch valve and a second pinch valve, wherein the first pinch valve has a first position that receives one of the at least one syringe inlets therethrough **at a position located between the at least one syringe and the at least one fluid reservoir connected by the at least one syringe inlet for control of fluid therebetween**, and has a second position that receives one of the at least one disposable tubes therethrough **at a position located between the at least one catheter and the at least one syringe connected by the at least one disposable tube for control of fluid therebetween**, and wherein the second pinch valve has a first position that receives the catheter outlet therethrough **at a position located between the catheter outlet and the at least one syringe connected by the at least one disposable tube for control of fluid therebetween**, and has a second position that receives the waste outlet therethrough **at a position located between the waste outlet and the at least one syringe connected by the at least one disposable tube for control of fluid therebetween.**

Thus, according to claim 41, "at least one syringe inlet" passes through the pinch valve, and "one of the at least one disposable tubes" passes through the pinch valve with the pinch valves required to be located between the devices (fluid reservoir, syringe inlet, catheter, syringe, and waste outlet).

For the reasons set forth above for claim 1 with regard to the requirement of **pinch valves located between devices for control of fluid flow therebetween in the system** in Applicants' invention, it is respectfully submitted that claims 41 and 42, as amended, are patentable, and the rejection of claims 41 and 42 as unpatentable over Lang in view of Fahy et al. under 35 U.S.C. § 103(a) is overcome.

V. The Rejection of Claims 10 and 11 Under 35 U.S.C. § 103(a) as Unpatentable over Reilly et al. in View of Fahy et al. and Further in View of Lang is Overcome

Claims 10 and 11 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Reilly et al. in view of Fahy et al., and further in view of Lang. The Examiner stated that Reilly et al. combined with Fahy et al. does not disclose multiple syringes with multiple valves associated with each syringe, but that Lang does disclose multiple syringes and multiple valves, and that "it would have been obvious to one of ordinary skill in the art to combine the system of Reilly et al. and Fahy et al. with the teachings of Lang because Lang discloses the benefit of having multiple syringes with multiple valves to allow better regulation and control of many different types of medication, especially medication that are incompatible infusion solutions (column 2, lines 17-30)."

To combine references, there must be a motivation or suggestion to combine the references. Respectfully, the Examiner did not provide such motivation or suggestion. The system of Reilly et al. is specifically directed toward delivery of a single toxic or hazardous drug. Such a drug must be kept apart from any other substance, and, thus, Reilly et al. takes special precautions for such isolation – including isolation of the fluid subsystem from any other substance. The system of Lang, on the other hand, discloses a system for handling many drugs – the fluid subsystem of which will have more than one drug flowing therethrough. Respectfully, there is nothing in Reilly et al. to suggest a system for delivery of multiple toxic of hazardous drugs, and there is nothing in Lang to suggest a system for delivery of toxic or hazardous drugs. Therefore, it is inappropriate to combine Reilly et al. and Lang as suggested by the Examiner.

Without regard to whether it is appropriate to combine Reilly et al. and Lang, neither Reilly et al. nor Lang nor Fahy et al., alone or in combination, suggest the use of **pinch valves located between devices in the fluid system for control of fluid therebetween** as required in Applicants' invention. Specifically, claim 1, as amended, and upon which claims 10 and 11 depend, require a pinch valve located between a catheter and a syringe for control of fluid between the catheter and syringe, as do claims 10 and 11. As previously discussed herein, pinch valves provide several advantages. Thus, respectfully, the absence of any disclosure, teaching, or suggestion in Reilly et al., Lang, or Fahy et al., either alone or in combination, means that claims 10 and 11 are patentable, and the rejection of claims 10 and 11 under 35 U.S.C. § 103(a) as unpatentable over Reilly et al. in view of Fahy et al. and further in view of Lang is overcome.

CONCLUSION

For all the foregoing reasons, it is respectfully submitted that the Applicants have made a patentable contribution to the art and that this response places the above-identified application in condition for allowance. Favorable reconsideration and allowance of this application is respectfully requested.

In the event the Applicants have inadvertently overlooked the need for an extension of time or payment of an additional fee, the Applicants conditionally petition therefor, and authorize any fee deficiency to be charged to deposit account 09-0007.

Sincerely,

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